



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MD1367
Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: Customs Entry No: ATO-0029516-5
Products: Fish Roe

WARNING LETTER

FLA-98-79

September 23, 1998

Mr. Goirgio Del Rossi
Gulf Harbor Trading, Inc.
3707 Toledo Street
Coral Gables, Florida 33134-6455

Dear Mr. Janco:

The Food and Drug Administration (FDA) attempted to examine a shipment of fish roe offered for entry into the United States by your firm on or about June 30, 1998, under the above referenced entry numbers and determined that these shipments were not available for FDA examination. Title 21, Code of Federal Regulations (21 CFR) Part 1.90, requires the importer to hold an entry intact pending receipt of a "May Proceed" notice or "Notice of Release" from FDA. We have requested the U. S. Customs Service (Customs) to order redelivery of these shipments (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

Mr. Goirgio Del Rossi
Page 2
September 23, 1998

Your written reply should be addressed to the Food and Drug Administration, Attention: Benjamin L. England, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a large, stylized 'D' and 'T'.

Douglas D. Tolen
Director, Florida District

Enclosure